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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,059	11/20/2000	Roy W. Jackson	50124/005001	1634

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/582,059

Applicant(s)

JACKSON ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-12,14,16,19-25,28,29,31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-12,14,19-25,28,29,31,33 and 34 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1625

### **DETAILED ACTION**

1. Claims 1-3, 5, 7-12, 14, 16, 19-25, 28, 29, 31, 33-34 are pending. Claims 18 and 32 have been canceled according to the amendment filed on 2-13-2003. Claims 4, 6, 13, 15, 17 and 30 have been canceled according to the amendment filed on 6-5-2002. Claims 26, 27 have been canceled according to the amendment filed on 8-13-2001.

#### ***Claim Rejections - 35 USC § 102***

2. The 102 (b) rejection over Maeda is withdrawn for claims 7, 31 because the claims has incorporated the limitation of specific YN moieties, and the charged group being amidino or guanidine, thereby setting demarcation from the prior art compound having an amido moiety.

3. The 102 (b) rejection over Atsumi (3950346) is withdrawn for claims 7, 31 because the claims has incorporated the limitation of specific YN moieties, and the charged group being amidino or guanidine, thereby setting a demarcation from the prior art compound having an amido moiety.

#### ***Claim Rejections - 35 USC § 103***

4. The rejection for Claims 7, 31 under 35 U.S.C. 103(a) as being unpatentable over Atsumi (3950346) is withdrawn because the claims has incorporated the limitation of specific YN moieties, and the charged group being amidino or guanidine, thereby setting a demarcation from the prior art compound having an amido moiety. Lacking is the motivation to modify the prior art compound to arrive at the instant invention.

#### ***Claim Rejections - 35 USC § 112(2)***

5. The 112 second paragraph rejection for Claims 1-3, 5, 7-12, 16, 18-25, 28, 29, 31-33 are withdrawn in view of the amendment.

Art Unit: 1625

***Claim Rejections - 35 USC § 112(1)***

6. The rejection for Claims 1-3, 5, 18 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification is withdrawn in view of the amendment.

7. The enablement rejection for Claims 1, 23-25, 33 under 35 U.S.C. 112, first paragraph is maintained for reasons of record. Applicant has amended the spacer to be '1-6 atoms' without defining what these atoms are. Without the full description, one of ordinary skill in the art would require undue experimentation to make the compound as claimed.

***Duplicate claims***

8. The cancellation of claim 32 has rendered moot the warning that should claim 24 be found allowable, claim 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

***Claim Rejections - 35 USC § 112(1)***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7-12, 14, 19-25, 28, 29, 31, 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Q of YNQ in claim 1 is not defined in the claim and it is not described in the specification. Applicant has recited page 4, lines 14 to 26 for support of the amendment. However, only YN-R or Y<sup>1</sup>NRR<sup>4</sup> with specific definitions for R and R<sup>4</sup> are disclosed.

Art Unit: 1625

b. 'R1 and R3 together form an alkylene or alkenylene of from 2 to 4 carbon atoms to complete a ring including two nitrogen atoms' of claims 7, 8 has no description in the specification, even though the imidazolyl of claim 9 falls within this genus.

c.  $\text{YN}(\text{CH}_2)_n\text{-NH}_2$  of claims 19, 34,  $\text{YN}(\text{CH}_2)_n\text{-(NH)}_{0-1}\text{-CN}$  of claims 20-22, the compound of formula V of claim 34, and the reactions thereof, are not described in the specification.

The rejection is applicable to claims dependent on the above claims.

### ***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 7-12, 14, 19-25, 28, 29, 31, 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1, second to last line, the term 'comprising' in 'opoid of formula YN-Q comprising' is open-ended and is therefore indefinite.

b. Claim 19, it is unclear how the recited process would make compounds of claim 7 other than those wherein Z is  $\text{NR}_3$  and wherein R2 and R3 are both H.

c. Claims 20, 21, 22 it is unclear how the recited process would make compounds of claim 7 other than those wherein Z is  $\text{NR}_3$  and wherein R2 is alkyl or H and R3 is H.

The rejection is applicable to claims dependent on the above claims.

### ***Allowable Subject Matter***

11. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1625

Jackson's compound 23 has disilyl protecting groups, which are absent in the instant. Jackson's compound has low opiate receptor activity, and has been shown to cross the blood brain barrier to elicit CNS activity whereas the instant has analgesic activity with reduced or little CNS side effects. Furthermore, Jackson is inoperative art. The instant compound is therefore unobvious over the compound of Jackson.

### *Conclusion*

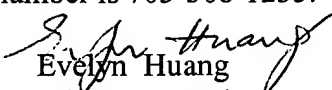
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

April 24, 2003